

REMARKS

Claims 1, 4-8, 11, 14, 19-21, 24, 28-30 and 35-40 are pending in the present case. Applicants note with appreciation that, in the Office Communication mailed June 29, 2009, the Examiner withdrew a number of prior rejections. In the same office action, the Examiner maintained rejection of Claims 1, 4-8, 11, 14, 19-21, 24, 28-30, and 35-37 under 35 U.S.C. §103, and rejected new claims 38-40 under the same section, as allegedly being unpatentable over Lapidus, *et al.*, (US 6,143,529; 11/7/00) in view of Hromadnikova et al (BMC Pregnancy and Childbirth, 5/28/02, 2(4):1-5). Applicants respectfully disagree with this rejection for the reasons set forth below.

35 U.S.C. §103

Section 2143.03 of the MPEP requires the "consideration" of every claim feature in an obviousness determination. To render a claim unpatentable, however, the Office must do more than merely "consider" each and every feature for this claim. Instead, the asserted combination of references must also teach or suggest *each and every claim feature*. See *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (emphasis added) (to establish prima facie obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art). Indeed, as the Board of Patent Appeal and Interferences has confirmed, a proper obviousness determination requires that an Examiner make "a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art." See *In re Wada and Murphy*, Appeal 2007-3733, *citing In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis in original). Further, the necessary presence of all claim features is axiomatic, since the Supreme Court has long held that obviousness is a question of law based on underlying factual inquiries, including ... ascertaining the differences between *the claimed invention* and the prior art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) (emphasis added). Indeed, Section 904 of the MPEP instructs Examiners to conduct an art search that covers "the invention *as described and claimed*." (emphasis added). Lastly, Applicants respectfully direct attention to MPEP § 2143, the instructions of which buttress the conclusion that obviousness requires at least a suggestion of all of the features of a claim, since the Supreme Court in *KSR Int'l v. Teleflex Inc.* stated that "there

must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

In sum, it remains well-settled law that obviousness requires at least a suggestion of all of the features in a claim. See *In re Wada and Murphy, citing CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) and *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

As noted by the Examiner, Lapidus *et al.* teaches a method for identifying a patient as a candidate for additional colorectal cancer testing comprising the steps of: determining a quantitative amount of patient genomic DNA in a stool sample comprising shed cells and shed cellular debris, wherein the quantitative amount is determined by using quantitative PCR to measure an amount of nucleic acid fragments amplified from shed cells and shed cell debris, wherein a higher amount of amplifiable genomic DNA in a stool sample. Lapidus teaches a number of different indicia associated with the presence of colon cancer, including analysis of the ratio of DNA longer than 200 bp to the amount of DNA of less than about 200 bp in length (see, *e.g.*, Lapidus column 4, lines 45-47, and claim 1). The instant claims, however, are directed to a measurement of the number of genome equivalents of DNA that is in fragments having length of less than 200 bp, without regard to the amount of, or ratio to DNA in fragments longer than 200 bp in the sample. Nowhere does Lapidus teach or suggest that analysis DNA fragments having length of less than 200 bp alone - without the measure of longer DNA in the same sample - could be used as an indicator of colon cancer, or that measurement of the number of genome equivalents of DNA in fragments having lengths of less than 200 bp would be sufficient to identify a patient as a candidate for additional colorectal cancer testing, especially in a stool sample. Lapidus particularly emphasizes the difficulty of detecting cancer indicia in the heterogeneous environment of a stool sample. As noted by Lapidus, colorectal cancer is thought to affect only about 1% of colonic epithelial cells, making stool samples highly heterogeneous. See, *e.g.*, Lapidus column 2, lines 1-5. With Lapidus teaching that determining the amount of DNA of longer than 200 bp is required for identifying a patient as a candidate for additional colorectal cancer testing

based on a stool sample, one of skill in the art would hardly be led to conduct tests on stool samples measuring only DNA having length below the minimum indicated size.

The Examiner asserts that the deficiency in Lapidus with respect to measurement of genome equivalents is made up in the teachings of Hromadnikova *et al.* (Office Action, page 5). While Hromadnikova does teach determination of "genome equivalents", the teachings of Hromadnikova are not sufficient to make up for all of the deficiencies of Lapidus discussed above. Hromadnikova fails to teach or suggest determination of the number of genome equivalents of nucleic acid fragments having length of 200 bp or less in a stool sample, or that such determination could be used as a method of identifying a patient as a candidate for additional colorectal cancer testing. As such, even if the teachings of Hromadnikova are combined with the teachings of Lapidus (Applicants do not concede that such a combination is proper or would be made by one of skill in the art), the combination fails to teach or suggest each and every feature of the instant claims.

While Applicants do not acquiesce that the other elements necessary for establishing prima facie obviousness have been met, Applicants submit that the combination of Lapidus and Hromadnikova does not teach or suggest all the features of Claims 1, 4-8, 11, 14, 19-21, 24, 28-30 and 35-40, and cited art therefore fails to establish prima facie obviousness. Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that all grounds for rejection have been addressed and Applicants' claims should be passed to allowance. If the Examiner wishes to discuss this case, Applicants encourage the Examiner to call the undersigned at 608-662-1277 at the Examiner's convenience.

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